

INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(PCT Article 36 and Rule 70)

Applicant's or agent's file reference JNR/P33149	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA/416)	
International application No. PCT/EP 03/13074	International filing date (day/month/year) 18.11.2003	Priority date (day/month/year) 20.11.2002
International Patent Classification (IPC) or both national classification and IPC A61M15/00		
Applicant GLAXO GROUP LIMITED et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.



2. This REPORT consists of a total of 5 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the opinion
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 13.05.2004	Date of completion of this report 21.01.2005
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Vanttinen, H Telephone No. +49 89 2399-7442 

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. **PCT/EP 03/13074**

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, Pages

1-10 as originally filed

Claims, Numbers

1-43 as originally filed

Drawings, Sheets

1/3-3/3 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
☐ the language of publication of the international application (under Rule 48.3(b)).
☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority in written form.
☐ furnished subsequently to this Authority in computer readable form.
☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
☐ the claims, Nos.:
☐ the drawings, sheets:

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. **PCT/EP 03/13074**

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 42,43

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 42,43 are so unclear that no meaningful opinion could be formed (*specify*):

see separate sheet

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the said claims Nos. 42,43

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the Standard.

☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	12,13,32,33,35-41
	No: Claims	1-11,14-31,34
Inventive step (IS)	Yes: Claims	12,13,32,33,35-41
	No: Claims	1-11,14-31,34
Industrial applicability (IA)	Yes: Claims	1-41
	No: Claims	

2. Citations and explanations

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. **PCT/EP 03/13074**

see separate sheet

1 Concerning Item V

- 1.1 The subject-matter of claim 1 has been defined using such broad terms that a simple flexible tube falls under the wording of claim 1. A tube can hold powder inside between the ends of the tube and the tube can be moved to a sealing state by crimping the ends of the tube.
- 1.2 In addition, US-A-1 410 556 (D1) discloses a capsule being suitable for holding a powder, even though only liquid medicament is mentioned. Said capsule has a first opening (2) and a second opening (opening of member 6). In a filling state (see Fig. 2) there is a fluid communication through the capsule and in the sealing state (see Fig. 1) the internal chamber is sealed. Thus, the subject-matter of claim 1 is not novel over D1.
- 1.3 Also the technical features of claims 2-11, 14-31 and 34 appear to be disclosed by D1.
- 1.4 The technical features of claims 12, 13, 32, 33 and 35 do not appear to be derivable from any of the cited documents in an obvious manner. Thus, they appear to meet the requirements of Article 33(2) and (3) PCT.
- 1.5 The method according to the independent method claim 36 appears to meet the requirements of Article 33(2) and (3) PCT, because the method steps b) and c) do not appear to be disclosed by or derivable in an obvious manner from any of the cited documents. Thus, the subject-matter of claim 36 and its dependent claims 37-41 appear to meet the requirements of Article 33(2) and (3) PCT.
- 1.5 The industrial applicability (Article 33(4) PCT) of a device according to the claims 1-35 and of a method according to claims 36-41 is self-evident.

2 Concerning Item III

Claims 42 and 43 attempt to define their subject-matters only by referring to the figures. Such definition does not allow the skilled person to determine the technical features of the device and the scope of the protection. Therefore and because said claims have not been searched, they have not been examined in respect of Article 33(2)-(4) PCT.